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Response Under 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1742

Attorney Docket No. NDC-15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alan Pelton et al.

Serial No.: 09/760,595 Art Unit: 1742

Filed : January 16, 2001 Examiner: H. Wilkins III

For : MEDICAL DEVICES, PARTICULARLY STENTS, AND METHODS FOR THEIR MANUFACTURE

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231 on

October 1, 2002
(Date of Deposit)

Paul A. Coletti
(Name of applicant, assignee, or Registered Representative)

(Signature)

October 1, 2002
(Date of Signature)

Commissioner for Patents
Washington, D.C. 20231

PARTIAL RESPONSE TO FINAL REJECTION DATED SEPTEMBER 4, 2002

Applicants herewith provide a signed Information Disclosure Statement matching the Information Disclosure Statement filed June 26, 2002. A copy of the first page and page 3 of the Office Action are also provided.

Applicants respectfully request entry of the Information Disclosure Statement.

A response to the merits of the Office Action will follow according to the ground rules of the MPEP.

Respectfully submitted,

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October 1, 2002

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,595	01/16/2001	Alan R. Pelton	NDC-15	4295

7590 09/04/2002

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EXAMINER
WILKINS III, HARRY D

ART UNIT	PAPER NUMBER
1742	10

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Corrected Notice of Allowability
Final Rej
&
Notice of Appeal
12/4/02

Office Action Summary

Application No.	Applicant(s)	
09/760,595	PELTON ET AL.	
Examiner	**Art Unit**	
Harry D Wilkins, III	1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *26 June 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The objections to the claims have been withdrawn in view of the amendment to the claims.

2. The rejection under 35 USC 112, first paragraph has been withdrawn in view of applicant's remarks filed 26 June 2002.

Drawings

3. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 26 June 2002 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Information Disclosure Statement

4. The proposed information disclosure statement filed on 26 June 2002 (paper no. 7) has not been entered because it is unsigned.

Since the above mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME LIMIT MAY BE GRANTED UNDER 37 CFR 1.136(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto (JP 03-140452) in view of Pelton et al (US 5,843,244).

Sakamoto teaches (see English abstract) that a titanium containing alloy wire is subjected to an oxidizing treatment that selectively oxidizes the titanium, thus forming a surface layer of titanium oxide (TiO_2). Sakamoto teaches (see Figure and definition of "W" on page 2) that the wire is made of a Ni-Ti alloy. Sakamoto teaches (see page 2, upper right) that the alloy has 50-at% Ti (and, thus, 50 at% Ni). This equates to about 55 wt% Ni. Sakamoto teaches that the Ni-Ti alloy is in the form of a wire.

Sakamoto does not expressly teach that the wire is used as a medical device, such as a stent.

Pelton et al teach (see abstract) a method of treating a Ni-Ti shape memory alloy. Pelton et al teach (see paragraph spanning cols 4 and 5) that the inventive method is used to make stents from Ni-Ti shape memory alloys.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the Ni-Ti wire of Sakamoto as a stent because it has shape memory characteristics which allow it to perform the functions of a stent. A stent is a medical device.

Though Sakamoto is silent as to the depth of the oxide surface layer, the product and process of Sakamoto is substantially identical, i.e.-preferentially forming a TiO_2 surface layer on a NiTi alloy, therefore, one of ordinary skill in the art would have found

it obvious to optimize the depth of the oxide surface layer in order to maximize the adhesion of the oxide scale and to maximize the reduction in surface Ni.

Regarding claim 2, Sakamoto teaches that the surface layer oxide is TiO_2. Thus, the surface contains no Ni.

Regarding claims 3, 4, 5, 7 and 8, each of these claims is a product-by-process claim. Applicant is reminded that for product-by-process claims, the prior art still anticipates the claimed invention, even if made by a materially different method.

Regarding claim 6, Sakamoto teaches (see Figure and definition of "W" on page 2) that the wire is made of a Ni-Ti alloy.

Regarding claims 9 and 10, as stated above, Sakamoto teaches that the alloy contains about 55 wt% Ni.

Regarding claims 11 and 13, Pelton et al teach using a Ni-Ti wire as a stent. Therefore, it would have been obvious to one of ordinary skill in the art to have used the Ni-Ti wire of Sakamoto as a stent because it has shape memory characteristics which allow it to perform the functions of a stent.

Regarding claim 12, Sakamoto teaches a method whereby the surface of a Ni-Ti alloy is exposed to a surface treatment ~~which causes the se~~lective formation of a titanium oxide surface layer. This causes the surface to have a "reduced" Ni content with respect to the bulk content of Ni.

7. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto in view of Pelton et al as applied to claims 1-13 above, and further in view of Suzuki et al (US 4,612,061).

As described above, Sakamoto in view of Pelton et al teach the invention substantially as claimed. However, Sakamoto does not teach that the component is exposed to superheated steam.

Suzuki et al teaches (see abstract) a method of forming an oxide surface layer on a metal. The method includes exposing the metal a steam atmosphere.

The oxidation step of Sakamoto and the steam oxidation step of Suzuki et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the steam exposure method of Suzuki et al for the formation of the oxide surface layer in the method of Sakamoto because the two processes are functional equivalents.

Regarding claims 15 and 16, changes in temperature, concentrations, or other process conditions of an old process does not impart patentability unless the recited ranges are critical, i.e., they produce a new and unexpected result. In re Aller et al (CCPA 1955) 220 F2d 454, 105 USPQ 233. Thus, it would have been within the expected skill of a routineer in the art to have optimized the treatment time and temperature of the steam exposure in order to create a surface layer that is substantially all TiO_2.

8. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto in view of Pelton et al as applied to claims 1-13 above, and further in view of Mayer et al (US 4,148,699).

As described above, Sakamoto in view of Pelton et al teach the invention substantially as claimed. However, Sakamoto does not teach that the component is immersed in a chemical solution bath for at least about 0.5 hours.

Mayer et al teach (see claim 1) a surface treatment method for stainless steel that includes, as step (3), the formation of an oxide coating by treatment of the workpiece in an aqueous nitric acid bath.

The oxidation step of Sakamoto and the nitric acid bath step of Suzuki et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the nitric acid bath method of Mayer et al for the formation of the oxide surface layer in the method of Sakamoto because the two processes are functional equivalents.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto in view of Pelton et al as applied to claims 1-13 above, and further in view of Nitowski et al (US 5,277,788).

As described above, Sakamoto in view of Pelton et al teach the invention substantially as claimed. However, Sakamoto does not teach that the component is included as an anode in a solution bath with a current running there through.

Nitowski et al teach (see abstract) that a substrate is anodized (i.e.-used as an anode in a solution bath with current running therethrough) to produce an oxide surface layer.

The oxidation step of Sakamoto and the anodizing step of Nitowski et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the anodizing method of Nitowski et al for the formation of the oxide surface layer in the method of Sakamoto because the two processes are functional equivalents.

Response to Arguments

10. Applicant's arguments filed 26 June 2002 have been fully considered but they are not persuasive. Applicant has argued that:

a. the limitation that the surface region is 10 nm deep is not disclosed by Sakamoto or any of the other references; and,

b. there is no clear disclosure in Sakamoto that the step of oxidizing causes the Ni content of the alloy in the surface region to be reduced compared to that in the remainder of the component.

In response to Applicant's first argument, though the limitation that the surface region with reduced Ni is 10 nm deep is not found in the prior art, one of ordinary skill in the art would have found it obvious to optimize the depth of the oxidizing treatment to maximize the adhesion of the oxide scale. Applicant has the burden of showing that the claimed range is critical compared to the cited prior art (i.e.-only at 10 nm is some unexpected, beneficial property achieved).

In response to Applicant's second argument, though Sakamoto does not expressly teach that the surface Ni content is reduced, because the method disclosed by Sakamoto preferentially forms a TiO_2 oxide scale, one of ordinary skill in the art would have expected the method to "reduce" the amount of the Ni in the surface region compared to the remainder of the component. The surface region would be entirely TiO_2, leaving no Ni in the surface region.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harry D Wilkins, III whose telephone number is 703-305-9927. The examiner can normally be reached on M-Th 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy V King can be reached on 703-308-1146. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Harry D Wilkins, III
Examiner
Art Unit 1742

hdw
August 28, 2002

ROY KING
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Application Number	09/760,595
Filing Date	January 16, 2001
First Named Inventor	Alan Pelton et al.
Group Art Unit	1742
Examiner Name	H. Wilkins III
Attorney Docket Number	NDC-15

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
HW		TREPANIER, C. et al., *Improvement of the Corrosion Resistance of NiiTi Stents by Surface Treatments*, Materials Research Society Symposium Proceedings, 1996, Vol. 459, pp. 362-368	
HW		TREPANIER, C., et al., *Effect of Modification of Oxide Layer on NiiTi Stent Corrosion Resistance*, John Wiley & Sons, Inc. J Biomed Mater Res (Appl Biomater) 43, 1998, pp. 433-440	

Examiner Signature	Harry D. Wilkins III	Date Considered	8/28/02

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.
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